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14. ABSTRACT: F-18 labeled estradiol has been found to be useful in the evaluation of estrogen receptor status in patients with breast cancer using PET. To investigate this further, this project's objectives are: • To evaluate the use of estrogen-like ligands labeled with positron emitters in preoperatively determining the ER status of breast cancer using PET. • Correlate the ER positivity seen on PET imaging with ER positivity found on pathologic analysis of the surgical specimen. This "proof-of-concept" study is a pilot study designed to determine feasibility of PET imaging. If the study is positive, i.e. if more than 70% of ER+ lesions are positive on PET imaging, we will subsequently plan a study with outcome parameters. PET scans will be graded as negative or positive (defined as tumor:normal uptake ratios of >1.5:1) and ER status will also be graded as negative or positive (defined as staining of > 5% tumor cells in an average high power field). Paired t-test comparison of tumor IHC and PET findings will be carried out. Gamma well counting will be used to quantify uptake of radioactivity in tumor and normal tissue including serum, and expressed as percent injected dose/gram. Serum estradiol is being measured to observe a possible relationship between serum estradiol levels and targeting of radiotracer.					
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Table of Contents

Cover.....	
SF 298.....	2
Table of Contents.....	3
Introduction.....	4
Body.....	5

Introduction

As stated above F-18 labeled estradiol has been found to be useful in the evaluation of estrogen receptor status in patients with breast cancer using PET. To investigate this further, this project's objectives are:

- To evaluate the use of estrogen-like ligands labeled with positron emitters in preoperatively determining the ER status of breast cancer using PET.
- Correlate the ER positivity seen on PET imaging with ER positivity found on pathologic analysis of the surgical specimen.

This "proof-of-concept" study is a pilot study designed to determine feasibility of PET imaging. If the study is positive, i.e. if more than 70% of ER+ lesions are positive on PET imaging, we will subsequently plan a study with outcome parameters.

PET scans will be graded as negative or positive (defined as tumor:normal uptake ratios of $>1.5:1$) and ER status will also be graded as negative or positive (defined as staining of $> 5\%$ tumor cells in an average high power field). Paired t-test comparison of tumor IHC and PET findings will be carried out.

Gamma well counting will be used to quantify uptake of radioactivity in tumor and normal tissue including serum, and expressed as percent injected dose/gram.

Serum estradiol is being measured to observe a possible relationship between serum estradiol levels and targeting of radiotracer.

Body

There have been no patients accrued to this trial to date. Delays occurred due to inquiries for clarification by our internal Research Council, Institutional Review Board and Radioactive Drug Research Committee (RDRC). A complete rewrite was required to address questions as raised by Committee Members. The protocol has been revised and was approved by the final committee- RDRC on 12/21/05. The study was subsequently placed on administrative hold while the PI was out on maternity leave. The IRB approved protocol and consent was forwarded to the Army and reviewed by the U.S. Army Medical Research and Materiel Command Human Subjects Research Review Board (HSRRB) on March 22, 2006. Recommendations and required changes were addressed and the revised protocol and consent were submitted to HSRRB on May 10, 2006. We are still awaiting final approval by the HSRRB. Once approved by HSRRB, an amendment incorporating HSRRB's suggested changes will be submitted to our IRB to be reviewed. After IRB approval enrollment will begin. We anticipate enrolling the first five patients within 3-6 months and will plan to review the results with the RDRC committee in February 2007.